

REMARKS

Status of the Claims

Claims 1-25 were originally pending. Claims 4, 5, 8-13, 21 and 25 have been withdrawn from consideration in response to a restriction requirement and are now cancelled. Claims 1-3, 6, 7, 14-20 and 22-24 are now pending. Claims 1-3, 6, 7, 14-20 and 22-24 have been rejected. Claims 3, 6, 7, 17, 19, and 20 have been amended. Reconsideration of the application is respectfully requested.

Objection to the Specification

The specification has been objected to as containing the use of the trademark "PreservCyt Solution" as well as other trademarks, without capitalization. As the owner of the trademark PresevCyt®, the Assignee of the current patent application does not object to the use of the trademark in the current form. As noted in MPEP 608.01, the proper use of trademarks in a patent application may be denoted by either the capitalization each letter of the word or the use of a proper trademark symbol. The Applicant respectfully requests that the objection to the specification should be withdrawn.

The Rejections Under 35 U.S.C. §112, Second Paragraph Should be Withdrawn

Claims 3, 7, 17 and 19 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner states that there is no antecedent basis for the limitation "the sensor" in Claim 3, "the target" in Claim 7, and "the first label" in Claim 19.

Claims 3 and 7 have been amended and thus rendering the Examiner's rejection moot. Claim 19 does not have the limitation of "the first label", however Claim 20 does. Applicant assumes that the Examiner meant to object to Claim 20. As such, the Applicant has amended Claim 20 thus rendering the prospective rejection of Claim 20 moot.

The Examiner also rejected Claim 17 under 35 U.S.C. 112, second paragraph, as being vague and indefinite for reciting a limitation of washing the sample prior to the determination step. The Examiner states that the claim is unclear since "it is unclear how this is accomplished if the target molecule is not part of a cell." The Applicant disagrees.

Claim 17 has no limitation as to the origin of the target molecule. The target molecule could have cellular origins or it could be extracellular. The washing step used in Claim 17 is merely to remove non-specifically bound molecules from the sensor molecule. Although the Applicant believes that the rejection of Claim 17 under 35 U.S.C. 112, second paragraph has been traversed, in order to expedite prosecution, Claim 17 has been amended to clarify the washing step, thus rendering the Examiner's rejection moot.

Accordingly, for the reasons stated above, Claims 3, 7, 17 and 19 now satisfy the requirements of 35 U.S.C. 112, second paragraph. Withdrawal of the rejection is requested.

The Rejections Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 1-3, 6-7, 17, 19-20, and 22-23 have been rejected under 35 U.S.C.102(b) as being anticipated by Bruchez *et al.* (USP No. 6,274,323). The Examiner argues that Bruchez *et al.* teaches a method for assaying a sample for the presence of a target molecule just as required by the claims of the present invention. The Applicant respectfully traverses this rejection.

Bruchez *et al.* does not anticipate the presently claimed invention for two reasons. First,

Bruchez *et al.* does not disclose all of the limitations of the claims. Second, Bruchez *et al.* does not enable the present claims.

Bruchez *et al.* does not disclose all of the limitations of Claim 1.

Bruchez *et al.* cannot anticipate Claim1 because it does not disclose all of the limitations of Claim1. Bruchez *et al.* does not teach a method for assaying a sample for the presence of a target molecule comprising: providing a liquid sample suspected of comprising the target molecule; contacting the sample with a filter, said filter comprising a sensor molecule attached thereto, said sensor molecule capable of specifically binding to the target molecule, if present; passing the sample transversely through said filter using a pressure-controlling apparatus under conditions that allow the sensor molecule to bind to the target molecule; recovering the remaining liquid sample; and determining whether the target has bound to the sensor.

Specifically, Bruchez *et al.* does not teach or suggest a filter comprising an attached sensor molecule. Bruchez *et al.* also does not teach or suggest a method of passing a liquid sample transversely through a filter using a pressure-controlling apparatus under conditions that allow the sensor molecule to bind to a target molecule within the liquid sample. The Examiner argues that the Applicant's specification defines a filter to be any material to which a sensor can be attached and which does not adversely impact the sample (page 18, lines 1-6). However, the following sentence in the specification further describes the filter of the present invention as having pore sizes suitable for allowing the desired portion of the sample to pass through the filter (see page 18, lines 6-7).

In particular, the typical pore sizes of the filter fall within the range of about 0.2 to about 20 microns (see page 18, lines 11-12). Thus, the Examiner's argument that the filter described in the present invention can be made of "any material to which a sensor can be attached" is incomplete. By definition, a filter must be comprised of material that must be porous enough to allow liquid and some, if not all, biological material to pass through. As such, Bruchez *et al.* does not suggest or teach the use of a filter. Bruchez *et al.* describes a host of exemplary solid supports including needles, pins, solid fibers, beads, and hydrophobic polymers, none of which are described or suggested to have the capability of functioning as a filter (see column 22, lines 52-61). Because Bruchez *et al.* lacks any such teaching it cannot anticipate any of the present claims, all which include a step of passing a sample through a filter.

Bruchez *et al.* also does not teach or suggest passing a liquid sample transversely through a filter using a pressure-controlling apparatus under conditions that allow the sensor molecule to bind to a target molecule within the liquid sample. The Examiner argues that apparatuses such as capillaries, hollow fibers, needles, pins, and the like are capable of controlling the pressure of a liquid sample by limiting the rate and amount of sample taken in. The Applicant disagrees.

The Applicant's claim specifically describes a method of passing a fluid sample transversely through a filter using a pressure-controlled apparatus. The so called "apparatuses" mentioned by the Examiner are actually solid supports, not separate apparatuses (see column 22, lines 52-56). Nowhere in Bruchez *et al.* is there any suggestion of teaching of using a pressure-controlled apparatus to pass liquid transversely across a filter. Because Bruchez *et al.* lacks any such teaching it cannot anticipate any of the present claims, all which include a step of using a pressure-controlled apparatus to pass a sample through a filter.

Accordingly, for the reasons stated above, Claim 1 and all claims depending therefrom are allowable. Withdrawal of the rejection is requested.

Bruchez *et al.* cannot anticipate the claims because it is not enabling

As noted previously, Bruchez *et al.* does not suggest or teach the use of a filter. Bruchez *et al.* describes numerous solid supports including pellets, disks, capillaries, needles, pins, solid fibers, beads, gels, and hydrophobic polymers. Even assuming, *arguendo*, that some of the solid supports described in Bruchez *et al.* have the limited ability to allow liquid to pass through them, there is simply no teaching or suggestion in Bruchez *et al.* to pass a liquid sample transversely through the solid support to selectively separate biological components of the sample. Without such a teaching, one skilled in the art would have no motivation to use such solid supports as filters.

Likewise, Bruchez *et al.* also does not teach or suggest passing a liquid sample transversely through a filter using a pressure-controlling apparatus under conditions that allow the sensor molecule to bind to a target molecule within the liquid sample. Even assuming, *arguendo*, that some of the apparatuses such as capillaries, hollow fibers, needles, pins, and the like are capable of controlling the pressure of a liquid sample, there is simply no teaching or suggestion in Bruchez *et al.* to use the apparatuses to pass a liquid sample transversely through a filter or that the apparatuses are capable of performing such a function..

For the reasons outline above, it is Applicant's position that Bruchez *et al.* does not enable the present claims. "[I]nvalidity by anticipation requires that the four corners of a single, prior art document describe every limitation of the claimed invention, either expressly or

inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.” *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272 (Fed. Cir. 2000) (emphasis added). *Bruchez et al.* does not meet this standard.

Accordingly, for the reasons stated above, Claim 1 and all claims depending therefrom are allowable. Withdrawal of the rejection is requested.

In view of the forgoing, Applicants respectfully request that the Examiner withdraw the pending rejections under 35 U.S.C. §102(b).

The Rejections Under 35 U.S.C. §103(a) Should be Withdrawn

Claim 18 was rejected under 35 U.S.C. 103(a) as being unpatentable over *Bruchez et al.* (USP No. 6,274,323) in view of *Hurley et al.* (USP No. 5,256,571). The Applicant respectfully traverses this rejection.

The Examiner argues that it would have been prima facie obvious at the time the invention was made to modify the method of assaying a sample for the presence of a target molecule as taught by *Bruchez et al.* to further include using a water-soluble alcohol preserving solution as taught by *Hurley et al.*

The Applicant restates the argument made above that *Bruchez et al.* either alone or in combination, does not teach or suggest passing a liquid sample transversely through a filter using a pressure-controlling apparatus under conditions that allow the sensor molecule to bind to a target molecule within the liquid sample. The use of water-soluble alcohol preserving solution is not relevant and needs not to be addressed since *Bruchez et al.* either alone or in combination, does not teach or suggest all the limitations of the present invention. More specifically, *Bruchez*

et al. does not teach or suggest a filter comprising an attached sensor molecule. Bruchez *et al.* also does not teach or suggest a method of passing a liquid sample transversely through a filter using a pressure-controlling apparatus under conditions that allow the sensor molecule to bind to a target molecule within the liquid sample. Thus, Claim 18 is not rendered obvious by Bruchez *et al.*


For all of the above-discussed reasons, Applicant submits that the rejection of Claim 18 under 35 U.S.C. §103(a) have been overcome. Withdrawal of the rejection is requested.

Conclusion

In light of the amendments and arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited. It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 11.025011.

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